SUPPLEMENT H

TECHNICAL PROCEDURES IN NUCLEAR MEDICINE SERVICE

1. TP NM-1, Technical Procedure for Assay of 99-Mo Contamination

2. TP NM-2, Radiopharmaceutical Testing and Quality Control

3. TP NM-3, Technical Procedure for Radiation Protection

4. TP NM-4, Technical Procedure for Dose Calibration

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NUCLEAR MEDICINE SERVICE
DEPARTMENT OF RADIOLOGY
WALTER REED ARMY MEDICAL CENTER

Technical Procedure
Number-NM1

DEC 2 1973

TECHNICAL PROCEDURE FOR ASSAY OF ^{99}Mo CONTAMINATION OF ^{99m}Tc

1. PURPOSE: This technical procedure provides a method for the determination of 99Mo content and the calibration of 99mTc for human use.

2. INSTRUMENTATION: The thyroid uptake system consisting of a 2 x 2 inch Sodium Iodide (th) crystal probe and a scintillation spectrometer will be used for all measurements.

3. QUALITY CONTROL: Routine practice has been established for daily checks of voltage calibration, linearity, efficiency and background.

4. MATERIALS: The lead "pig" labeled "For use in determining 99Mo contamination in 99mTc" should be used. This pig has side wall shielding of 2.5 cm of lead. The 137Cs standard source calibrated as 113.7 microcurie of 99Molybdenum is used as a standard.

5. PROCEDURE: (step 1) Set spectrometer settings for 99Mo
Gain: 8
Base: 600
Window: 200

(step 2) Place assay pig beneath the thyroid probe at a distance 5cm from the face of the collimator with the center of the assay pig aligned with the center of the collimator. (step 3) Take 5 serial counts of 2 minutes each and average. Enter in assay log as 2 minutes background counts. (step 4) Place the collecting vial containing the total 99mTc eluate (at least 25 millicuries) in the assay pig. Position as for step 2.

(step 5) Take 5 serial counts of 2 minutes each and average. Enter in assay log as 2 minutes 99Mo counts. (step 6) Remove collecting vial and replace with 137Cs standard. Collect 5 serial 2 minutes counts and average. Enter in assay log as 2 minute standard counts.

(step 7) Calculations:

$$99\text{Mo Activity} = \frac{AxBx6.3}{\frac{C}{D}}$$

Where A= net cp2m of 99mTc sample
B= activity of 137Cs sample in microcuries
C= net cp2m of 137Cs standard
6.3= conversion factor 137Cs activity to equivalent 99Mo activity
D= number of millicuries of 99mTc in collecting vial

If the assay reveals more than 1 uCi of 99Mo in 1 mCi of 99mTc, or more than 5 uCi of 99Mo per dose, the material will not be given to humans.

99mTc Assay. The assay for 99mTc will be done in the mediac dose calibrator set for 99mTc. Total activity will be noted and entered with volume in the Radiopharmaceutical RP log.

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*TECHNICAL PROCEDURE
NO. NM2

RADIOPHARMACEUTICAL TESTING AND QUALITY CONTROL

1. PURPOSE. To establish general procedures for the routine testing of radiopharmaceuticals at WRAMC.

2. Radiopharmaceuticals manufactured or compounded for human use will be prepared under the supervision of the Chief, Nuclear Medicine Service. Control numbers will be assigned to each batch produced and quality control records and appropriate control samples will be maintained.

3. Stock solutions used in compounding radiopharmaceuticals are prepared in the I.V. Section of the hospital pharmacy using pyrogen tested chemicals, sterilized by membrane filtration, gas or autoclaving and tested for pyrogenicity and sterility by U.S.P. methods. Stocks are identified by lot numbers and are shown by lot, when used for compounding in the radiopharmacy log book.

4. Testing for assay, identity, quality and purity will be accomplished prior to patient administration. When possible, sterility and pyrogenicity testing of parenterally administered products will be accomplished prior to administration to humans. If prior testing for sterility and pyrogenicity is not possible because of short half-life, testing will be accomplished after administration. Upon presentation of a statement signed by the administering physician attesting that a medical emergency exists, with the concurrence of the Chief, Nuclear Medicine Service, a radiopharmaceutical normally tested for sterility and pyrogenicity may be administered prior to such testing.

5. Not less than six trial batches of new radiopharmaceutical products or new methods of production will be completely tested prior to administration to humans.

6. Radiopharmaceuticals for oral administration will be routinely or periodically tested for sterility and pyrogenicity when deemed appropriate by Chief, Nuclear Medicine Service.

7. The United States Pharmacopoeia (USP) prescribed method of sterility and pyrogenicity testing will be used.

8. Testing for assay, identity, quality, and purity of a radiopharmaceutical when not prescribed by the USP will be in keeping with best practices. This may include, but is not limited to pH, clarity, odor, volume, specific activity, chemical analysis, pharmacological effectiveness, liquid scintillation counting, gamma spectroscopy, 4 pi beta counting, dose calibration by free air ionization chamber technique, and total dose integration.

*THIS TECHNICAL PROCEDURE SUPERSEDES SOP No. 3-R-1, WRAMC, DATED 14 OCT 69.

9. Products containing radioisotope labelled ("tagged") compounds will be tested by radiochromatography to determine the location of the radioisotope and percent bonding.

10. Test producers for individual radiopharmaceuticals will be included in the protocols submitted to the WRAMC Radioisotope Committee for approval.

The following radiopharmaceuticals are compounded in the Radiopharmacy Section, Nuclear Medicine Service, WRAMC.

Technetium-99m Sulfur Colloid
Technetium-99m Macroaggregated Albumin
Technetium-99m Human Serum Albumin
Technetium-99m Diethylenetriaminepentaacetic Acid
Technetium-99m Polyphosphate

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DEPARTMENT OF RADIOLOGY
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Technical Procedure
Number-NM3

30 MAY 1974

TECHNICAL PROCEDURE FOR RADIATION PROTECTION

1. PURPOSE: The purpose of this technical procedure is to show the placement of shielding within the hot lab to provide adequate radiation protection.

2. STORAGE CAVE: The storage cave consists of a lazy susan type storage area divided into 4 segments per shelf. There are 4 shelves for a total of 16 segments. In front of the lazy susan there is a stainless steel cabinet 32 in depth and 36" high. The cabinet is backed by 1 1/4 inch of lead shielding and 1/16th inch of steel. The sides and top of the storage are made of concrete six inches thick and protrude into an unoccupied area with no pedestrian traffic. The top of the cabinet is 32x40". The lazy susan is operated by remote control by a 3 way switch located in front of the cave. When not in use, the lazy susan is placed in its lowest position to provide maximum shielding.

3. GENERATOR STORAGE: A wall of lead bricks (2x8 inches) shall extend end to end across the cave entrance on top of the cabinet. This wall shall be ten inches in height and divided into 2 sections, by a lead wall extending from the outer wall towards the lazy susan. A lead sleeve of 3/4inch thickness shall be provided to house the most recently received generator. The older generator will be placed behind that sleeve and held one week, and then sent to health physics

for disposal. No more then 2 generators will be on hand at any one time.

4. FUME HOOD: A storage well, consisting of lead bricks will be fabricated of sufficient size for storage of radiopharmaceuticals prepared for daily use. This well should be 10 inches in height by 2 inches thick. The dimensions of the well should be flexible.

5. QUALITY CONTROL: To ensure adequate radiation protection, readings from a model E-120 Geiger counter should not exceed 1 mr/hr at the face of the shielding.

6. MONITORING: WRAMC Health Physics personnel will make periodic checks to ensure compliance with appropriate regulations.

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Technical Procedure Number-NM4 — 31 May 1974

TECHNICAL PROCEDURE FOR DOSE CALIBRATION

1. PURPOSE: This technical procedure describes the methodology for preparing and calculating the dosage for radiopharmaceuticals.

2. MATERIAL HANDLING: All vials containing radioactive materials used in the manufacturing of radiopharmaceuticals will be placed in lead pigs.

3. PERSONNEL HANDLING: Personnel handling radioactive materials will wear disposable plastic gloves, wrist film badge and a whole body film badge.

4. CALCULATING ACTIVITY: The procedure for calculating the eluted fractions of 99mTechnetium is described in Tech Procedure NM1. The 99mTechnetium used in compounding radiopharmaceuticals will be first measured in the Mediac Dose calibrator set at 99mTc X 10. Immediately following compounding the finished product will again be assayed in the dose calibrator. The radiopharmacist will then calculate the specific activity and note in the RP log the activity per milliliter and the time of assay.

5. INDIVIDUAL DOSES: The technologist preparing individual doses will first note the radiopharmaceutical to be used and the activity prescribed on the patient prescription card. He will then use the dosage record portion of the prescription card to arithmetically calculate the amount required in milliliters. After drawing up the desired amount, he will place the syringe in the Mediac dose calibrator set at the required setting. The reading should

be within plus or minus 2% of the calculated dose.

6. QUALITY CONTROL: The Mediac dose Calibrator will be calibrated daily using the ^{57}Cobalt source on ^{99m}Tc setting (the net reading, gross minus background, should be 186 ± 10%) and the ^{137}Cs source on ^{137}Cs setting (the net reading should be 0.205 ± 10%). If the values for either setting are outside of 10% range, a serviceman should be notified to recalibrate the instrument.

NOTE: As the ^{57}Cobalt source has a half-life of 270 days, the 208 figure should be corrected for decay. This reading was obtained on 31 May 1974. All corrections should be from this date.

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